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Attorneys for Plaintiffs
LIFESCAN, INC.
LIFESCAN SCOTLAND, LTD.

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION**

LIFESCAN, INC., and
LIFESCAN SCOTLAND, LTD.,

Plaintiff,

V.

SHASTA TECHNOLOGIES, LLC,
DECISION DIAGNOSTICS CORP.,
PHARMATECH SOLUTIONS, INC., and
CONDUCTIVE TECHNOLOGIES, INC.

Defendants.

Case No. CV11-04494-EJD (PSG)

**FIRST AMENDED COMPLAINT
DEMAND FOR JURY TRIAL**

FIRST AMENDED COMPLAINT
NO. CV11-04494-EJD (PSG)

1 Plaintiffs LifeScan, Inc. ("LifeScan") and LifeScan Scotland, Ltd. ("LifeScan
 2 Scotland") (collectively "Plaintiffs") hereby file this First Amended Complaint against
 3 Defendants Shasta Technologies, LLC ("Shasta"), Decision Diagnostics Corp. ("DDC") (formerly
 4 known as InstaCare Corp.), PharmaTech Solutions, Inc. ("PharmaTech"), and Conductive
 5 Technologies, Inc. ("Conductive") (collectively the "Defendants") and allege as follows:

6 **NATURE OF THE ACTION**

7 1. This is an action for damages and injunctive relief to remedy infringement
 8 of U.S. Patent Nos. 5,708,247 ("the '247 Patent"), 6,241,862 ("the '862 Patent"), and 7,250,105
 9 ("the '105 Patent") (collectively, "the patents-in-suit"). This action arises under the patent laws of
 10 the United States, 35 U.S.C. § 101, *et seq.* The inventions at issue involve disposable blood
 11 glucose test strips for sufferers of diabetes.

12 **THE PARTIES**

13 2. Plaintiff LifeScan is a corporation organized under the laws of the State of California, having its headquarters and principal place of business at 1000 Gibraltar Drive, Milpitas, California 95035.

14 3. Plaintiff LifeScan Scotland is a private limited company organized under the laws of the United Kingdom, having its headquarters and principal place of business at Beechwood Park North, Inverness, Inverness-Shire, IV2 3ED, Scotland, United Kingdom.

15 4. On information and belief, Shasta is a corporation organized under the laws of the State of Oregon, having a principal place of business at 7340 Hunziker Road, Suite 205, Tigard, Oregon 97223.

16 5. On information and belief, DDC is a corporation organized under the laws of the State of Nevada, having a principal place of business at 2660 Townsgate Road, Suite 300, Westlake Village, California 91361. DDC formerly was known as InstaCare Corp. ("InstaCare").

17 6. On information and belief, PharmaTech is a corporation organized under the laws of the State of Nevada, having a principal place of business at 2660 Townsgate Road, Suite 300, Westlake Village, California 91361.

7. On information and belief, Conductive is a corporation organized under the laws of the State of Pennsylvania, having a principal place of business located at 935 Borom Road, York, Pennsylvania, 17404.

JURISDICTION AND VENUE

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

9. On information and belief, this Court has personal jurisdiction over Shasta because Shasta has had continuous, systematic, and substantial contacts with the State of California, including doing business in this judicial district and having a place of business within this judicial district at 3257 Highway 128, Calistoga, California 94515.

10. On information and belief, this Court has personal jurisdiction over DDC because DDC has had continuous, systematic, and substantial contacts with the State of California, including doing business in this judicial district and having a principal place of business within the State of California at 2660 Townsgate Road, Suite 300, Westlake Village, California 91351.

11. On information and belief, this Court has personal jurisdiction over PharmaTech because PharmaTech has had continuous, systematic, and substantial contacts with the State of California, including doing business in this judicial district and having a principal place of business with the State of California at 2660 Townsgate Road, Suite 300, Westlake Village, California 91351.

12. On information and belief, this Court has personal jurisdiction over Conductive because Conductive has had continuous, systematic, and substantial contacts with the State of California, including regularly doing business in this judicial district, and has entered into a contract with a Shasta, DDC and or PharmaTech to supply products made by infringing Lifescan Scotland's patents into this judicial district.

13. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 and 1400(b).

BACKGROUND

14. On January 13, 1998, the U.S. Patent and Trademark Office ("the PTO") issued the '247 Patent, entitled "Disposable Glucose Test Strips, and Methods and Compositions for Making Same." A true and correct copy of the '247 Patent is attached as Exhibit A.

15. LifeScan Scotland holds title to the '247 Patent.

16. LifeScan holds an exclusive license from LifeScan Scotland to sell and offer to sell in the United States products practicing the '247 Patent, sell and offer to sell in the United States products made by processes practicing the '247 Patent, use the invention of the '247 Patent in the United States, and sue and recover damages for infringement, including past infringement, of the '247 Patent.

17. On June 5, 2001, the PTO issued the '862 Patent, entitled "Disposable Test Strips With Integrated Reagent/Blood Separation Layer." A true and correct copy of the '862 Patent is attached as Exhibit B.

18. LifeScan Scotland holds title to the '862 Patent.

19. LifeScan holds an exclusive license from LifeScan Scotland to sell and offer to sell in the United States products practicing the '862 Patent, sell and offer to sell in the United States products made by processes practicing the '862 Patent, use the invention of the '862 Patent in the United States, and sue and recover damages for infringement, including past infringement, of the '862 Patent.

20. On July 31, 2007, the PTO issued the '105 Patent, entitled "Measurement of Substances in Liquids." A true and correct copy of the '105 Patent is attached as Exhibit C.

21. LifeScan Scotland holds title to the '105 Patent.

22. LifeScan holds an exclusive license from LifeScan Scotland to sell and offer to sell in the United States products practicing the '105 Patent, sell and offer to sell in the United States products made by processes practicing the '105 Patent, use the invention of the '105 Patent in the United States, and sue and recover damages for infringement, including past infringement, of the '105 Patent.

1 23. LifeScan sells strips for blood glucose testing under the name OneTouch®
2 Ultra®.

3 24. The OneTouch® Ultra® test strips practice one or more claims within the
4 scope of the patents-in-suit.

5 25. The OneTouch® Ultra® strips are designed for use with the OneTouch®
6 Ultra® family of glucose monitors, including the OneTouch® Ultra®, OneTouch® Ultra® 2,
7 OneTouch® UltraSmart®, OneTouch® UltraLink®, and OneTouch® UltraMini®.

8 26. The number of each of the patents-in-suit is marked on the packaging for
9 each OneTouch® Ultra® test strip or OneTouch® Ultra® glucose meter that is sold, offered for
10 sale, or imported into the United States by LifeScan. All OneTouch® Ultra® test strips made by
11 processes within the scope of one or more claims of the patents-in-suit that are sold, offered for
12 sale, or imported into the United States by LifeScan are marked with numbers of those patents-in-
13 suit in the manner prescribed by 35 U.S.C. § 287(a).

14 27. Shasta has applied to the U.S. Food and Drug Administration ("FDA") for
15 pre-market approval to sell a test strip for glucose diagnostics under the name "Shasta GenStrip."
16 The Shasta GenStrips is designed to work with the OneTouch® meters as a substitute for
17 LifeScan's OneTouch Ultra test strips.

18 28. On information and belief, Shasta is likely to receive FDA approval to sell
19 the Shasta GenStrips in the very near future, and intends to begin selling the Shasta GenStrip in
20 the United States when it receives FDA approval.

21 29. On information and belief, Shasta also has applied to various regulatory
22 bodies in other countries for permission to market the Shasta GenStrip in those countries.

23 30. On information and belief, Shasta and PharmaTech have entered an
24 agreement regarding the control, management, and distribution of Shasta GenStrip, including
25 distribution within the United States.

26 31. On information and belief, Shasta, PharmaTech and/or DDC have entered
27 an agreement with Conductive regarding the manufacture of Shasta GenStrip, including for
28 distribution within the United States.

1 32. On April 18, 2011, a press release was issued over PR Newswire entitled
 2 "InstaCare Subsidiary Signs New Agreement for Expanded Management and Sales of Shasta
 3 Genstrip Into the \$20 Billion Worldwide Diabetes Testing Market." (hereinafter the "April 18,
 4 2011 press release"). A copy of the April 18, 2011 press release is attached as Exhibit D.

5 33. The press release states as follows:

6
 7 LOS ANGELES, April 18, 2011 /PRNewswire/ -- InstaCare Corp.
 8 (OTCQB: ISCR) a leading provider of prescription diagnostics,
 9 home testing products for the chronically ill, a leading fulfillment
 10 provider of direct to patient diabetes programs, and a leading
 11 developer of revolutionary cell phone centric e-health products and
 12 technologies, today announced that its operating subsidiary, Pharma
 13 Tech Solutions, Inc., has significantly expanded its agreement to
 control, manage and distribute the novel at-home diagnostic
 product, ***the Shasta Genstrip. This diagnostic consumable is
 targeted at an existing, FDA-approved platform for in-home
 diabetes testing, the market leader in the \$20 billion worldwide
 market.***

14 The revised and expanded agreement provides Pharma Tech
 15 Solutions ("Pharma Tech") with worldwide distribution rights to all
 16 markets and complete control of the Genstrip diabetes diagnostic
 17 product, including regulatory responsibility with the US FDA,
 Medicare and Medicaid, plus the European Economic Area
 18 approval of the mandatory "CE" (Conformite Europeenne)
 conformance mark.

19 "This expanded agreement provides us with greater control and
 20 significantly broadens our market opportunity, accelerating our
 21 pathway to market and increasing the ultimate potential of this
 22 business line," commented Keith Berman, President of Pharma
 23 Tech Solutions, Inc. and CFO of InstaCare. "This increased control
 24 is of paramount importance, as it allows us to drive the regulatory
 25 approval process and better manage the overall initiative. We are
 26 moving with all due haste while simultaneously building a
 27 distribution, sales and marketing infrastructure necessary to support
 28 this game-changing product."

25 This new diagnostic product will be targeted at diabetics already a
 26 part of the world-wide at-home diabetes testing market estimated to
 27 exceed \$20 billion in 2010. ***Shasta Genstrip, an alternative test
 strip, is comparable to the existing diagnostic provided by the
 platform manufacturer, but priced at approximately one-half the
 cost.*** This new diagnostic, exclusively managed and distributed by

1 InstaCare's subsidiary, will be the sole competing product available
 2 on the market. Management anticipates substantial revenue streams
 3 and anticipates its market share to reach 7-10% by the end of 2012.
 4 The at-home diagnostic testing market is currently estimated to
 5 exceed \$20 billion globally in 2011 (more than \$10 billion in the
 6 U.S.). This market has grown historically at rates in excess of 25%
 7 per year.

8 *"This product is ideally suited for our business, as we will market
 9 Genstrip using strategies and tactics similar to the generic drug
 10 industry as we exploit the established diagnostic platform,"* Mr.
 11 Berman continued. *"The platform manufacturer has spent
 12 considerable resources to create a razor/razor blade model with a
 13 high-value, moderate-cost consumable. We will leverage this
 14 effort and the installed base to sell and distribute a much lower-
 15 cost consumable for this market, and we have also added
 16 exclusive international distribution rights as well as entry into
 17 domestic direct to patient (mail order) markets.* This unique
 18 product brings state-of-the-art science and a much lower cost
 19 structure, and a much higher profit base, estimated to be greater
 20 than 200% higher than those margins provided under our earlier
 21 agreement with Shasta Technologies, LLC."

22 For more information about InstaCare Corp., Pharma Tech
 23 Solutions, Inc., Shasta Genstrip and/or its revolutionary MD@Hand
 24 cell phone centric technologies, please visit the InstaCare web site
 25 www.instacare.net or www.pharmatechdirect.com, or call the
 26 company at (805) 446-2973.

27 (Emphasis Added).

28 34. On information and belief, the "platform manufacturer" referred to in the
 April 18, 2011 press release is LifeScan and the "existing diagnostic provided by the platform
 manufacturer" is the OneTouch® Ultra® test strip.

30 35. Shasta has designed Shasta Genstrips to be compatible with the
 OneTouch® Ultra® family of glucose monitors. The Shasta Genstrips, their method of
 manufacture, and their use with the OneTouch® Ultra® family of glucose meters are all within
 the scope of one or more claims of the patents-in-suit. On information and belief, Defendants
 make, sell, use, or offer to sell Shasta Genstrips within the United States or threaten to do so.
 Plaintiffs are entitled to relief for such acts under 35 U.S.C. § 271.

1 36. On May 24, 2011, DDC (then known as InstaCare) issued a sales guidance
2 regarding Shasta Genstrips, projecting 2011 sales at \$41.8 million and 2012 sales at \$206.6
3 million. A copy of the sales guidance is attached as Exhibit E.

4 37. Beginning on June 24 2011, LifeScan contacted the Defendants regarding,
5 *inter alia*, the April 18, 2011 press release and to seek additional information regarding Shasta
6 Genstrips.

7 38. On June 24, 2011, LifeScan sent a letter to DDC (then known as InstaCare)
8 with copies to Shasta and Conductive. A copy of the letter is attached as Exhibit F.

9 39. In the letter, LifeScan expressed its concerns about the Defendants'
10 activities in light of the April 18th press release including its belief that those activities constitute
11 infringement of various LifeScan patents:

12 LifeScan is also aware that Shasta Technologies, LLC ("Shasta")
13 has approached at least one authorized distributor of LifeScan
14 products seeking to enlist that entity as a distributor of Shasta
15 Genstrips. It appears from the press release and Shasta's activities
16 that the Shasta Genstrip will be marketed for use with LifeScan's
17 meters. LifeScan believes that it is likely that the current and future
18 activities of Shasta in manufacturing, selling and offering for sale
19 the Shasta Genstrip constitute infringement of certain United States
20 patents owned by LifeScan relating to test strips and methods of
21 their use and manufacture including U.S. Patent Nos. 5,708,247;
22 5,951,836; 6,241,862; 7,112,265; 7,250,105 and 7,462,265.

20 40. On information and belief, Defendants have taken substantial steps in
21 preparation to make Shasta Genstrips or have Shasta Genstrips made, including, but not limited to
22 designing the Shasta Genstrip, applying for FDA approval of the Shasta Genstrip, arranging for
23 distribution of the Shasta Genstrip, and stockpiling Shasta Genstrips in the United States for
24 distribution upon regulatory approval.

25 41. Under information and belief, the Defendants' entry into the test strip
26 market is imminent.

COUNT I

Declaratory Judgment Action for Infringement of the '247 Patent

42. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 41 hereof, as if fully set forth herein.

43. On information and belief, Defendants have actively induced infringement and threaten to actively induce infringement one or more claims of the '247 patent, either literally or under the doctrine of equivalents, by having Shasta Genstrips made for distribution within the United States.

44. The Defendants' activities have placed LifeScan under a reasonable apprehension that the Defendants will infringe and/or actively induce infringement of the '247 patent. There now exists a justiciable case and controversy for adjudication by the Court.

45. The aforesaid acts, plans, and intentions of the Defendants give rise to an actual existing controversy of which this Court has jurisdiction between Plaintiffs and the Defendants. Plaintiffs seek relief against the Defendants' acts of threatened infringement to avoid irreparable injury which would result if Plaintiffs waited until commencement of full scale commercial marketing of the Shasta Genstrip.

46. On information and belief, the acts of infringement of the patents-in-suit by the Defendants, unless promptly enjoined, will cause irreparable loss, injury, and damage to Plaintiffs and will prevent Plaintiffs from enjoying the exclusive rights granted by the '247 patent for the full remaining term.

47. On information and belief, the Defendants' infringement of the '247 patent has been willful.

COUNT II

Declaratory Judgment Action for Infringement of the '862 Patent

48. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 47 hereof, as if fully set forth herein.

49. On information and belief, Defendants have actively induced infringement and threaten to actively induce infringement one or more claims of the '862 patent, either literally

or under the doctrine of equivalents, by having Shasta Genstrips made for distribution within the United States.

50. The Defendants' activities have placed LifeScan under a reasonable apprehension that the Defendants will infringe and/or actively induce infringement of the '862 patent. There now exists a justiciable case and controversy for adjudication by the Court.

51. The aforesaid acts, plans, and intentions of the Defendants give rise to an actual existing controversy of which this Court has jurisdiction between Plaintiffs and the Defendants. Plaintiffs seek relief against the Defendants' acts of threatened infringement to avoid irreparable injury which would result if Plaintiffs waited until commencement of full scale commercial marketing of the Shasta Genstrip.

52. On information and belief, the acts of infringement of the patents-in-suit by the Defendants, unless promptly enjoined, will cause irreparable loss, injury, and damage to Plaintiffs and will prevent Plaintiffs from enjoying the exclusive rights granted by the '862 patent for the full remaining term.

53. On information and belief, the Defendants' infringement of the '862 patent has been willful.

COUNT III

Declaratory Judgment Action for Indirect Infringement of the '105 Patent

54. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 53 hereof, as if fully set forth herein.

55. On information and belief, Shasta, DDC and PharmaTech have threatened to indirectly infringe one or more claims of the '105 patent, either literally or under the doctrine of equivalents, by selling, and/or offering to sell Shasta Genstrips, which have no substantial noninfringing uses and are apparatuses for use in practicing a process covered by the '105 patent, while knowing that Shasta GenStrips to be especially made or especially adapted for use in infringement of the '105 patent, and are not staple articles or commodities of commerce suitable for substantial noninfringing use. The end-users (patients) using the strips with the LifeScan

1 Ultra® family of meters would be performing the direct infringement to which Defendants
2 contribute.

3 56. On information and belief, Shasta, DDC and PharmaTech have further
4 threatened to induce patients to infringe one or more claims of the '105 patent, either literally or
5 under the doctrine of equivalents, by instructing patients to use Shasta Genstrips with LifeScan
6 meters in a manner that would infringe the '105 patent.

7 57. The Defendants' activities have placed LifeScan under a reasonable
8 apprehension that the Defendants will contributorily infringe or induce infringement of the '105
9 patent. There now exists a justiciable case and controversy for adjudication by the Court.

10 58. The aforesaid acts, plans, and intentions of the Defendants give rise to an
11 actual existing controversy of which this Court has jurisdiction between Plaintiffs and the
12 Defendants. Plaintiffs seek relief against the Defendants' acts of threatened infringement to avoid
13 irreparable injury which would result if Plaintiffs waited until commencement of full scale
14 commercial marketing of the Shasta Genstrip.

15 59. On information and belief, the acts of infringement of the patents-in-suit by
16 the Defendants, unless promptly enjoined, will cause irreparable loss, injury, and damage to
17 Plaintiffs and will prevent Plaintiffs from enjoying the exclusive rights granted by the '105 patent
18 for the full remaining term.

19 60. On information and belief, the Defendants' infringement of the '105 patent
20 has been willful.

PRAYER

23 WHEREFORE, Plaintiffs demand judgment as follows and respectfully pray that
24 this Court:

- (b) An Order preliminarily and permanently enjoining each of the Defendants and their officers, agents, employees, and all others in concert or participation with them from further acts of infringement of the patents-in-suit;
- (c) An Order adjudging and decreeing that this case is exceptional;
- (d) An award of Plaintiffs' damages for infringement, with interest and trebled, pursuant to 35 U.S.C. § 284;
- (e) An award to Plaintiffs of its costs and expenses of this action as allowed by law, together with its reasonable attorneys' fees for bringing and prosecuting this action; and
- (f) Such other and further relief that the Court may deem just and proper.

1
2 **DEMAND FOR JURY TRIAL**
3

4 Plaintiffs LifeScan and LifeScan Scotland demand a trial by jury on each of their claims
5 for relief triable before a jury.
6

Dated: December 10, 2012

/s/ Eugene M. Gelernter
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